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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,451

03/11/2005

Giorgio Mari

P70454US0

2728

136 7590 09/19/2008

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EXAMINER

KIM, SUN U

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

09/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,451	Applicant(s) MARI ET AL.	
	Examiner JOHN KIM	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 12-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/9/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. Applicant's election of Group I (claims 1-11) in the reply filed on 7/24/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 12-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 7/24/08 as described above.

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the flow control means capable of carrying out the steps in claim 3 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

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be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to because the drawing does not have a legend, "Figure" or "Figure 1". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

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- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Currently, there is no "Brief Description of the Figure".

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-4, 7 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by

Stewart et al (US Patent No. 5,128,048).

Regarding claim 1, Stewart et al teach a device for separating blood into blood components comprising a collecting container (16), a first satellite container (32) connected, in fluid flow communication, to said collecting container (16) through a leukocyte filter (36), a

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second satellite container (28) connected, in fluid flow communication, with said collecting container (16) wherein the second satellite container (28) is connected to said collecting container (16) through said leukocyte filter (36), flow control means (36, 38, 42) being provided for allowing fluid flow from said collecting container (16) selectively into said first (32) or second (28) satellite container through said leukocyte filter (36) (see figures 2-3; col. 4, line 49 – col. 8, line 37). Materials such as blood, PRP, PRC, WB in claim 1 worked upon by the device does not limit the apparatus claims.

“Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim.” *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, “[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims.” *In re Young*, 75 F.2d 996, 25 USPQ 69 (CCPA 1935) (as restated in *In re Otto*, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)).

Regarding claim 2, Stewart et al teach that said second satellite container (28) is further connected to said collecting container (16) through conduit means (38) by-passing said filter (36), the said flow control means (38) being further capable of allowing fluid flow from said second satellite container (28) into said collecting container (16) only through said conduit means (38) by-passing said filter (36) (see figures 2, 4) .

Regarding claim 3, Stewart et al teach that the second satellite container (28) includes a blood additive “A” (see figure 2) and the flow control means (49, 48, 50, 52) are capable of achieving claimed steps by sheer locations of the flow control means in the respective conduits (see figures 2-4). Note that the method steps in claim 3 are an intended use. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed

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does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Regarding claim 4, Stewart et al teach first conduit means (26) connecting said collecting container (16) to said first satellite container (32) through said leukocyte filter (36), second conduit means branching off from said first conduit means (26) downstream of said leukocyte filter (36), thereby to connect said collecting container (16) to said second satellite container (16), and by-pass conduit means (38) branching off from said first conduit means (26), upstream of said leukocyte filter (36) and connected to said second conduit means (see figure 2).

Regarding claims 7 and 10, Stewart et al teach manually operated clamps (46, 47, 48, 50, 52, 54) (see col. 7, lines 29-33) associated with a separator device (36).

Regarding claim 9, Stewart et al teach clamp (50) i.e. valve means in the second conduit means leading to the second satellite container (28) (see figure 2).

Regarding claim 11, Stewart et al teach a third satellite container (30) connected in fluid flow communication with the first satellite container (32) (see figure 2).

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stewart et al as applied to claim 1 above, and further in view of Corbin et al (WO 03/063930 A1). Stewart et al teach a device for separating blood into blood components as described in above paragraph 7. Claims 5-6 essentially differ from the device of Stewart et al in reciting a sensor means controlling electromagnetic valve means for controlling the flow of components to respective satellite container by detection of the presence of blood component such as PRC. Corbin et al teach a device for separating blood into blood components comprising an optical sensor for detecting color of the blood components to close or open clamps (31, 32) on one or more branches (35, 36) to direct particular components to either a satellite bag (7) or a satellite bag (8) (see figure 5; page 17, lines 1-21). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a sensor means to control electromagnetic valve means in the device of Stewart et al for controlling the flow of components to respective satellite container by detection of the presence of blood component such as PRC as suggested by Corbin et al (see figure 5; page 17, lines 1-21).

10. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stewart et al as applied to claim 4 above, and further in view of Bischof et al (US Patent No. 7,264,608 B2). Stewart et al teach a device for separating blood into blood components as described in above paragraph 7. Claim 8 essentially differs from the device of Stewart et al in reciting a one-way valve provided in by-pass conduit allowing fluid flow only from second satellite container to collecting container. Bischof et al teach a device for separating blood into blood components comprising a one-way valve (V) provided in by-pass conduit (46) allowing fluid flow only from a satellite container (40) to collecting container (14) (see figures 2A-2B; col. 8, lines 32-47). It

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would have been obvious to a person of ordinary skill in the art at the time the invention was made to incorporate a one-way valve provided in by-pass conduit in the device of Stewart et al for allowing fluid flow only from second satellite container to collecting container so to prevent fluid flow in opposite direction as suggested by Bischof et al (see col. 8, lines 43-47).

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent No. 6,730,054 and 7,052,606 teach blood component separation apparatuses.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN KIM whose telephone number is (571)272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Sample can be reached on 571-272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John Kim/

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Primary Examiner, Art Unit 1797

JK

9/17/08